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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT PAPER NUMBER

1772

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/035,561	Applicant(s) WANG ET AL.	
	Examiner Christopher P. Bruenjes	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-63 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 37-63 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

WITHDRAWN REJECTIONS

1. All of the rejections regarding claims 31-36 of record in the previous Office Action mailed April 17, 2006 have been withdrawn due to Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 40, 42-57, 59-60, and 62-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 40, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof serve as a tie coat to adhere an additional layer to the substrate is not described

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in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen to act as a tie coat to adhere an additional layer to the substrate, but does not teach that acrylamide and/or N,N-dimethylacrylamide are used for this purpose.

Regarding claim 42, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof comprise functional groups to attach or bind physiologically or pharmacologically active agents is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise functional groups to attach or bind physiologically or pharmacologically active agents, but does not teach that acrylamide and/or N,N-dimethylacrylamide are used for this purpose.

Regarding claim 43, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof comprise a drug depot permitting the delivery of drugs from the graft polymer

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coating is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise a drug depot permitting the delivery of drugs from the graft polymer coating, but does not teach that acrylamide and/or N,N-dimethylacrylamide are used for this purpose.

Regarding claims 44 and 51, the specification does not teach that the graft polymerized coating is formed of pyridine or piperidine. The specification teaches some specific monomers such as 2- or 4-vinylpyridine, 4- or 2-methyl-5-vinylpyridine, and N-methyl-4-vinylpiperidine, but does not teach that any pyridine or piperidine may be used to form the coating as claimed in claims 44 and 51.

Regarding claims 47 and 54, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer serve as a tie coat to adhere an additional layer to the substrate is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating

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monomers can be chosen to act as a tie coat to adhere an additional layer to the substrate, but does not teach that any of the particular monomers of the Markush groups of claims 47 and 54 are used for this purpose.

Regarding claims 49 and 56, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer comprise functional groups to attach or bind physiologically or pharmacologically active agents is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise functional groups to attach or bind physiologically or pharmacologically active agents, but does not teach that any of the particular monomers of the Markush groups of claims 47 and 54 are used for this purpose.

Regarding claims 50 and 57, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer comprise a drug depot permitting the delivery of drugs from the graft polymer coating is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time

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the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise a drug depot permitting the delivery of drugs from the graft polymer coating, but does not teach that any of the particular monomers of the Markush groups of claims 47 and 54 are used for this purpose.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 44-57, 59-60, and 62-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 44 and 51, the limitation "the substrate comprises polymers or copolymers of polyurethanes, silicones, polyolefins, polyamides and latex" renders the claims vague and indefinite because it is not understood if the polymer or copolymer is meant to include all of the polymers listed or if this was meant to be a Markush group in which the phrase "selected from the group" should be added between "copolymers"

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and "of". For examination purposes the limitation will be considered a Markush group, since that appears to be the intent from the specification.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 37-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al (USPN 6,287,285).

Regarding claim 37, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). Note the substrate is not defined as being limited to only one layer or one type of material. Therefore, the substrate in its broadest reasonable

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interpretation could include a two-layered material. Michal et al teach a medical device formed of a substrate formed of the combination of a metal device (col.5, 1.42-44) containing a base coat over top of the metal device. Therefore, the base coat and metal device combined teach the substrate as claimed in Applicant's claim 37. The base coat comprises a binding component, which is formed of a isocyanate compound (col.8, 1.14-31), such as the urethane-acrylate taught in example 4 in column 16, lines 49-51). Thus, the substrate comprises copolymers of polyurethane. A plurality of monomer molecules are directly graft polymerized on at least one of the surfaces of the substrate, forming a top coat thereon (col.11, 1.5-10). The top coat is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an acrylamide, N,N-dimethylacrylamide, and mixtures thereof (col.8, 1.1-6).

Regarding claims 38-39, the medical device is a catheter, guide wire or medical instrument (col.2, 1.10-12), and the catheter is specifically a PTCA catheter (col.5, 1.53-56).

Regarding claims 40 and 42, the coating further comprises a linking agent that is placed between the substrate including the base coat and the therapeutic containing layer (col.2, 1.62-64). In this embodiment the linking agent is the plurality of monomer

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molecules and the therapeutic containing layer is the additional layer. The linking agent comprises a monomer or derivative selected from acrylamide or N,N-dimethylacrylamide (col.9, 1.46-56). Therefore, the coating represented by the linking agent layer of Michal et al serves as a tie coat to adhere the additional layer and has functional groups to attach or bind physiologically or pharmacologically active gents.

Regarding claim 41, the top coat is a hydrophilic agent made of acrylamide or N,N-dimethylacrylamide so inherently absorbs large quantities of water to provide moisture absorption or of lubricity.

Regarding claim 43, the coating comprises a drug depot permitting the delivery of drugs form the graft polymer coating (col.4, 1.10-65).

Regarding claims 58 and 61, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, 1.1-20).

Regarding claims 44 and 51, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). The substrate comprises polymers or copolymers of polyolefins or polyamides (col.5,

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1.34-41). The substrate has either a coating comprising a base coat and top coat system or a coating comprising a coating comprising a grafting component blended with the hydrophilic agent directly grafted to the substrate (col.11, 1.17-21 and col.12, 1.4-7). In the embodiment in which the coating comprises a base coat and top coat system, the base coat is a plurality of monomer molecules directly graft polymerized on the surface of the substrate, forming a coating thereon, wherein said coating on said substrate is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an alkylacrylate such as methacrylate (col.8, 1.28-31 and 1.50-54).

Regarding claims 45-46 and 52-53, the medical device is a catheter, guide wire or medical instrument (col.2, 1.10-12), and the catheter is specifically a PTCA catheter (col.5, 1.53-56).

Regarding claims 47 and 54, in the embodiment in which the coating is the base coat of the coating system the top coat forms an additional layer and the base coat serves as a tie coat to adhere the additional layer to the substrate.

Regarding claims 48 and 55, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating absorbs large quantities of water to provide moisture absorption or of lubricity.

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Regarding claims 49 and 56, in the embodiment in which the coating is the base coat of the coating system the top coat is a physiologically or pharmacologically active agent that is bonded to the base coat by the functional groups of the base coat.

Regarding claims 50 and 57, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating comprises drugs for delivery within the body, so the coating is a drug depot.

Regarding claims 59-60 and 62-63, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, 1.1-20).

Response to Arguments

8. Applicant's arguments with respect to claims 31-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
August 26, 2006


ALICIA CHEVALIER
PRIMARY EXAMINER